PARAMOL AF DAY CARE, CAPLETS

Patient package insert according to Pharmacists' Regulations (Preparations), 1986.

This medicine can be sold without a physician's prescription

Each caplet contains:

Paracetamol	500 mg
Pseudoephedrine HCl	25 mg

For list of excipients, please see section 6.

Read this entire leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask a physician or a pharmacist.

This medicine is dispensed without a physician's prescription and is intended for adults and children over 6 years only. Under this age, refer to a physician. Use in the correct manner. Consult a physician or a pharmacist if you need additional information.
Refer to a physician if the fever lasts for more than 3 days or if the symptoms of the illness get worse or do not improve within 3 days despite the use of the medicine or in any situation where new symptoms appear.

1. What is the medicine used for?

Symptomatic relief of cold and nasal congestion accompanied by fever and pain – day care medicine.

Therapeutic group:
- Paracetamol: analgesic and antipyretic.
- Pseudoephedrine Hydrochloride: sympathomimetic amine which relieves runny nose, nasal and ear congestion accompanying a cold and/or sinusitis.

2. Before you take the medicine:

Do not use the medicine if:

- You are pregnant or breastfeeding.
- You are hypersensitive to the active ingredients (paracetamol or pseudoephedrine), to other decongestants or to any of the other ingredients of this medicine.
- You are treated concomitantly with medicines from the following groups: monoamine oxidase inhibitors (MAOIs) (such as for the treatment of depression) or within 14 days of stopping treatment with them; other decongestants; beta-blockers (usually for the treatment of heart problems or hypertension).
- Do not use this medicine concomitantly with other paracetamol containing medicines (if you are not sure whether the medicine you are taking contains paracetamol, consult a physician or a pharmacist).
- If you suffer from the following diseases: severe hypertension, heart or vascular system disease, severe liver or kidney disease, overactive thyroid gland, increased intraocular pressure (glaucoma) or diabetes.

Special warnings regarding the use of this medicine:
- **Before taking Paramol Af Day Care tell a physician if:**
  - you suffer or have suffered in the past from impaired function of the heart and/or blood vessels, the liver, the kidney (such as tumour of the phaeochromocytoma type) or urinary tract, the thyroid gland.
  - you suffer or have suffered from increased intraocular pressure (glaucoma), enlargement of the prostate gland, diabetes, hypertension, restlessness, jaundice, alcoholism.
  - you are over 60 years old, since patients at this age may be sensitive to medicines of this type.
  - you are sensitive to any type of food or medicine.
  - you suffer from arthritis and have to take pain relievers every day.
- Do not use this medicine frequently without consulting a physician.
- Avoid taking a high dosage (even if at the recommended limit) of this medicine while fasting.
- This medicine contains paracetamol that may cause damage to the liver when: administered at a dosage higher than recommended or for an extended period, consuming alcoholic beverages during the treatment period or taking additional medicines that affect liver function.
- Do not take additional medicines for fever reduction and relief of pain, or cold medicines without consulting a physician or a pharmacist - in order to prevent paracetamol overdose/toxicity.
- Do not take other medicines of the "Paramol" group and/or additional paracetamol-containing medicines.
- If you have developed dermal side effects in the past resulting from taking products containing paracetamol, do not take products containing paracetamol to avoid recurrence of severe skin manifestations.

Please tell a physician or a pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements. Especially inform a physician or a pharmacist if you are taking:
- medicines stimulating the central nervous system (appetite suppressants, medicines used to treat asthma), medicines for the treatment of depression such as of the tricyclic group (Tricyclic antidepressants).
- anticoagulants (such as: warfarin).
- methyldopa and other antihypertensives and medicines used to treat heart problems (such as alpha blockers, digoxin); medicines that increase liver enzyme activity such as barbiturates, phenytoin or carbamazepine (used mainly for epilepsy, seizures, psychiatric problems); additional medicines for the treatment of seizures, antibiotics such as rifampicin or chloramphenicol, probenecid (for the treatment of gout).
- aspirin or other salicylates, cough and cold medicines (such as other medicines for the treatment of nasal congestion), additional pain relievers or fever reducing medicines, non-steroidal anti-inflammatory drugs, medicines for the treatment of migraines (Ergot alkaloids).
- metoclopramide or domperidone (for the treatment of nausea, vomiting and other stomach problems); cholestyramine (for reduction of the blood cholesterol level), medicines that may cause dryness of the mouth, oral contraceptives, oxytocin (for induction of labor and cessation of excessive bleeding after birth).
- do not take this medicine with other paracetamol-containing medicines, other decongestants, beta blockers, monoamine oxidase inhibitors (MAOIs) - see also section "Do not use the medicine if".

Use of this medicine and alcohol consumption:
Do not drink alcoholic beverages during the period of treatment with this medicine due to the increased risk of liver damage.

Pregnancy and breastfeeding:
Do not use this medicine if you are pregnant or breastfeeding.

Use in children:
This medicine is intended for adults and children over 6 years only, see section 3.
Parents should report to the physician about any side effects and any additional medicine given to the child.

3. How to use this medicine

Check with a physician or a pharmacist if you are not sure.

Unless otherwise instructed by the physician, the recommended dosage is usually:
Adults and children over 12 years of age: 1-2 caplets every 4-6 hours, up to 4 times a day.
Children 10-12 years of age: 1 caplet every 4-6 hours, up to 4 times a day.
Children 6-9 years of age: ½ caplet every 4-6 hours, up to 4 times a day.

In concomitant use with Paramol Af Night Care, replace a dose of **Paramol Af Day Care** with a dose of Paramol Af Night Care, and do not take it as a supplement to the maximum recommended dosage of **Paramol Af Day Care.**

Wait at least 4 hours before taking your next dose.

Do not exceed the dose recommended by the physician or pharmacist.

Swallow the medicine with water. It may be halved or crushed.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you! Do not induce vomiting unless explicitly instructed to do so by a physician! Even if you feel well, immediate treatment is essential because of the risk of developing severe liver damage.
Side effects may occur such as diarrhea, excessive sweating, poor appetite, nausea or vomiting, acute inflammation of the pancreas, abdominal cramps or pain, swelling, pain or tenderness in the upper abdomen, and they may not reflect the damage to the liver.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

4. Side effects:

Like all medicines, **Paramol Af Day Care** can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
The side effects may be more serious in the elderly.

Serious side effects:
Stop use of this medicine and refer to a physician immediately if the following appear:
- signs of allergy such as: rash, itching skin often accompanied by swelling of the face, lips, tongue, throat that may cause breathing difficulties / shortness of breath, swelling of the limbs.
- paracetamol can in rare cases cause the appearance of acute skin diseases that may have signs such as: redness, rash, blisters, mouth ulcers, peeling skin, extensive skin damage.
  Acute skin side effects may occur even if in the past you have taken medicines containing the active ingredient paracetamol without a problem.
- dryness of the mouth that may cause an increase in caries (it is recommended to use artificial saliva and keep oral hygiene), dizziness, nervousness, restlessness, sleep disorders, hallucinations, anxiety or paranoia, tremor, difficulty urinating in men especially when suffering from a prostate problem, kidney damage (with prolonged use), irregular heart rate, palpitations, hypertension.
- extreme fatigue, tendency to hemorrhages, bleeding and unusually high tendency of contracting infections - these symptoms may indicate blood system disorders (decrease in the number of blood cells) such as anemia, thrombocytopenia, pancytopenia, agranulocytosis, leukopenia or neutropenia.
- nausea, sudden loss of weight, poor appetite and yellowing of the skin and eyes.
- side effects resulting from overdose (see section "If you have accidentally taken a higher dosage").

Additional side effects:
Headache, bad dreams, feeling stressed or excited.

If any of the side effects gets worse, or if you suffer from side effects not mentioned in the leaflet, you should consult a physician.

5. How to store the medicine

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
Do not store above 25°C.
Store in the original package.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Povidone, Croscarmellose sodium, Hypromellose, Magnesium stearate, Titanium dioxide E171, Macrogol, Quinoline yellow aluminium lake E-104, FD&C blue no.1 aluminium lake E-133, Silica colloidal anhydrous, FD&C yellow no.6 aluminium lake E-110, Carnauba wax.
Each caplet contains approximately 1 mg of Sodium.

What the medicine looks like and contents of the package:
Green elongated caplet with a score line on both sides.
Each package contains 10, 20, 24, 30, 50 or 100 caplets in blisters.
Not all package sizes may be marketed.

Marketed exclusively by:
Super-Pharm (Israel) Ltd., PO Box 2171, Herzliya 4672516

Manufacturer and registration holder: DEXCEL Ltd., 1 Dexcel St., Or-Akiva 3060000, Israel

Drug registration number at the national medicines registry of the Ministry of Health: 127 93 30767 00.

This leaflet was checked and approved by the Ministry of Health in 04/2014.

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